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10/592,994	03/23/2007	Willem Ferdinand Nieuwenhuizen	VER-209XX	8473

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/592,994	NIEUWENHUIZEN ET AL.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/15/2006; 3/23/2007; 11/19/2007.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV, claims 9-10, drawn to a food item in the reply filed on 6/6/2008 is acknowledged. The traversal is on the ground(s) that examination of all of the claims is not seen as imposing an undue burden on the Examiner. This is not found persuasive because, as pointed out in the Lack of Unity determination of 3/27/2008, the technical feature linking the inventions has been taught in the prior art, the technical feature is not "special", and therefore the inventions are not so linked by the same or a corresponding technical feature to form a single general inventive concept (see Item 2 on p. 3 of the Restriction Requirement).

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant's election with traverse of phytosphingosine under option (i-a) in the reply filed on 6/6/2008 is acknowledged. The traversal is on the ground(s) that same as above. This is not found persuasive because see above.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-8, 11-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/6/2008.

Claim Rejections - 35 USC § 112 & 101

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 9-10 provide for the use of a food item with enhanced levels of a sphingolipid, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

8. The term "enhanced" in claims 9-10 is a relative term which renders the claims indefinite. The term "enhanced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

It is not clear what levels of sphingolipid are required to be considered “enhanced” levels; whether a concentrated food product, for example from yeast cells, would contain "enhanced levels" and fall within the metes and bounds of the claims, or

whether addition of phytosphingosine to the food product would be required, and in what amounts, in order to contain “enhanced” levels of the sphingolipid. It is also not clear whether one food with naturally occurring higher sphingolipid levels would be considered to contain "enhanced" levels, when compared to another food with naturally occurring lower sphingolipid levels.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 9 recites the food item is useful “for the prevention…of a disorder selected from the group consisting or insulin resistance, diabetes type 2 and Metabolic Syndrome”. Claim 10 recites the food item is useful “in a diet for lowering and/or preventing insulin resistance”. The embodiments within these claims of “prevention” of and “preventing” insulin resistance, diabetes type 2 and Metabolic Syndrome are not considered enabled. Prevention implies that the conditions will not develop, not just a delay of the onset of these conditions, or the reduction of the intensity of the symptoms associated with the conditions.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to use of a food item with enhanced levels of a sphingolipid, which includes the elected compound phytosphingosine, for the prevention and/or treatment of a disorder selected from the group consisting of insulin resistance, diabetes type 2 and Metabolic Syndrome; or in a diet for lowering and/or preventing insulin resistance. Thus, the claims taken together with the specification imply a diet with enhanced levels of phytosphingosine will prevent the conditions of insulin resistance, diabetes type 2 and metabolic syndrome, even in patients at high risk for developing these conditions.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Warner et al. ("Obesity-induced Insulin Resistance and Hyperglycemia: Etiologic Factors and Molecular Mechanisms"; 2008 Anesthesiology; 109:137-48) teach obesity is a major cause of type 2 diabetes, clinically evidenced as hyperglycemia; the altered

glucose homeostasis is caused by faulty signal transduction via the insulin signaling proteins, which results in decreased glucose uptake by the muscle, altered lipogenesis, and increased glucose output by the liver; the etiology of this derangement in insulin signaling is related to chronic inflammatory state, leading to the induction of inducible nitric oxide and reactive nitrogen species, which together cause posttranslational modifications in the signaling proteins (abstract); the role of the central nervous system in glucose homeostasis also has been established; multiprong therapies aimed at rectifying obesity-induced anamalies in both central nervous system and peripheral tissues may prove to be beneficial (abstract); therapeutic choices for treatment of insulin resistance, include excercise, life style modification, weight reduction and pharmacotherapy, which can attenuate the long-term cardiovascular and renal complications of hyperglycemia (p. 144, 2nd from last paragraph); multimodal, multifactorial interventions including behavior modifications and surgery have sustained beneficial effects on insulin sensitivity, cardiovascular complications and mortality (p. 146, 3rd paragraph).

This article illustrates the complexity of the conditions of the instant claims, including the complex etiology of faulty signaling, inflammation and the CNS on glucose homeostasis, and the hope that multifactorial therapies will be effective on insulin sensitivity. It would be unpredictable for a single sphingolipid addition to the diet to effectively prevent insulin resistance, diabetes type 2 and metabolic syndrome.

(5) The relative skill of those in the art:

The relative skill in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for reduction in levels of insulin resistance and improvement in insulin sensitivity when egg sphingomyelin or phytosphingosine are added to the diet of insulin resistant mice.

However, the specification does not provide evidence or convincing rationale that the addition of phytosphingosine to the diet will prevent insulin resistance, diabetes type 2 and metabolic syndrome, even in high risk individuals.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the complexity of the insulin resistance and the mechanistic factors, the hope that multiprong therapies including behavior modification will be effective treatment, and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

11. Claims 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is not have sufficient description of examples of "precursors" and "derivatives" of the elected compound to demonstrate possession of these extremely broad genus claims at the time the application was filed.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient."

MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to use of a food item with enhanced levels of a sphingolipid, which includes the elected compound phytosphingosine or a precursor, a derivative or a pharmaceutically acceptable salt thereof, for the prevention and/or treatment of a disorder selected from the group consisting of insulin resistance, diabetes type 2 and Metabolic Syndrome; or in a diet for lowering and/or preventing insulin resistance.

(1) Level of skill and knowledge in the art:

The level of skill and knowledge in the art are high.

(2) Partial structure:

The elected compound, compounds recited in claims 5-6 have been disclosed. Formulas I-III, as recited in the claims have also been disclosed.

(3) Physical and/or chemical properties and (4) Functional characteristics:

The compounds are active in treatment of insulin resistance, diabetes type 2, and metabolic syndrome.

(5) Method of making the claimed invention:

No method of making any precursor or derivative of the elected compound has been disclosed.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 9-10 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any precursor or derivative of the elected compound. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of the compounds of claims 5-6 and compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Nieuwenhuizen (WO 2004/064820 A2; filed 2004 Jan 20; IDS 11/29/2007 reference).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Nieuwenhuizen teaches compositions containing phytosphingosine, including food items and supplements with increased sphingolipid levels (abstract; Figure 1). The food items with enhanced levels of phytosphingosine would inherently be useful for the purposes recited in the instant claims of treating insulin resistance, diabetes type 2, and metabolic syndrome, as disclosed by applicant.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howell et al. (“The Preparation and Biological Significance of Phytosphingosines”; 2002;

Current Organic Chemistry; 6: 365-391; IDS 11/29/2007 reference) and Dewettinck et al. (WO 02/34062 A1; 2002; IDS 11/29/2007 reference).

Howell teaches phytosphingosine is bioactive and a potential heat stress signal in yeast cells, and some phytosphingolipids possess important physiological activities, such as high tumor potency (abstract; Figure 2). Howell does not teach phytosphingosine in a food product at enhanced levels. Dewettinck teaches food products enriched in phospho- and sphingolipids, such as milk (title, abstract); these "functional foods" have health promoting effects, foodstuffs that clearly resemble a medicine (p. 3, lines 20-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare food products with enhanced levels of the elected compound. The motivation would have been the health promoting effects of the product, including anti-tumor activity. The usefulness of the product recited in instant claims 9-10 would inherently be possessed by such a product, as disclosed by applicant.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 9-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-9 of copending Application No. 10/542838. Although the conflicting claims are not identical, they are not patentably distinct from each other because the food of animal feed of the copending claims recite the elected compound as one of several sphingolipid choices (except for copending claim 8, which is limited to the elected compound), and do not recite the uses of the instant claims; an amount range is required by copending claim 7, not required in the instant claims. It would have been obvious to select the instantly elected compound in the copending claims and to optimize the amount of the phytosphingosine in the instant claims, giving the same amount or range of amounts. The motivation to select the elected compound would have been the suitability for that purpose, as demonstrated by copending claim 8; the motivation to optimize the amounts would have been the routine optimization of conditions. The use recited in the instant claims would have been inherent for the obvious food or feed, as disclosed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-12 of copending Application No. 10/542845. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims differ from the instant claims in that the copending claims are not limited to the elected compound as one of several sphingolipid choices, and do not recite the uses of the instant claims; an amount range is required by copending claim 11, not required in the instant claims. It would have been obvious to select the instantly elected compound in the copending claims and to optimize the amount of the phytosphingosine in the instant claims, giving the same amount or range of amounts. The motivation to select the elected compound would have been the suitability for that purpose, as demonstrated by copending claim 5; the motivation to optimize the amounts would have been the routine optimization of conditions. The use recited in the instant claims would have been inherent for the obvious food or feed, as disclosed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Since two provisional rejections of double patenting have been made, and applicants are most familiar with their own patent applications, applicants must identify any other of their applications where double patenting with the instant claims may be present.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614